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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

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| Agency name | Board of Pharmacy, Department of Health Professions |
| Virginia Administrative Code (VAC) citation | 18VAC110-20 18VAC110-50 |
| Regulation title | Regulations Governing the Practice of Pharmacy Regulations Governing Wholesale Distributors, Manufacturers and Warehousemen |
| Action title | Change in renewal dates for pharmacies and permitted facilities |
| Date this document prepared | 6/4/08 |

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

- 1) Please explain why this is an "emergency situation" as described above.
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

Chapter 330 (HB1129) of the 2008 Acts of the Assembly eliminated the specified date of December 31 for renewal of various permits and registrations under the Board of Pharmacy and added that a date must be determined by the Board in regulation. The second enactment on

Chapter 330 requires that the Board promulgate regulations to implement the provisions of the act to be effective within 280 days of its enactment. Therefore, there is an “emergency situation” as defined in § 2.2-4011 of the Administrative Process Act.

All licenses, permits and registrations have expired on December 31st of each year, which has created an exceptional workload for staff during one period of time. The Board sought legislation to allow expiration dates for permitted or registered facilities to be set on dates different from those of licensed pharmacists or registered technicians to distribute the renewals.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The legal authority to promulgate the proposed regulation is found in Chapter 330 of the 2008 Acts of the Assembly (HB1129): §§ [54.1-3434](#), [54.1-3434.2](#), [54.1-3435](#), [54.1-3435.01](#), [54.1-3435.2](#), [54.1-3435.4](#), and [54.1-3439](#) of the Code of Virginia, relating to the expiration of various pharmacy licenses. The authority to promulgate regulations to set the renewal date for permitted and registered facilities is mandatory.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

All licenses, permits and registrations have expired on December 31st of each year, which has created an exceptional workload for staff during one period of time. The Board sought legislation to allow expiration dates for permitted or registered facilities to be set on dates different from those of licensed pharmacists or registered technicians. All facility permits or registrations that currently expire on December 31st; permits will continue to be in effect until the next renewal date as set by the Board in regulation. Resident and non-resident pharmacy permits will next expire on April 30, 2009, so they will get an extra four months on their permits. Manufacturers, wholesale distributors, warehouse, physicians permitted to practice pharmacy, medical equipment suppliers, humane societies, and controlled substance registrations will expire on February 28, 2009, so they will get an extra two months. The goal is to distribute the workload for Board and Department staff and to make it less burdensome for pharmacies, some of which pay the renewal for the pharmacy permit and all licensed or registered staff.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

A single expiration date means that the Board of Pharmacy staff annually renews all of its 20,000+ licenses at the same time. This creates a very unequal workload during this time of the year. Because of recent significant increases in numbers of licensees, the addition of registered pharmacy technicians, and increases in non-resident facility licenses, the Board's ability to renew licenses in a timely manner is being challenged. Even though a number of persons use on-line licensure renewal, many facilities choose not to do so, and non-residents facilities are not able to do this because of requirement to show proof of resident licensure and a pharmacist-in-charge who holds a Virginia license.

The action is necessary to protect the health and safety of the citizens because a staggered renewal system will assist staff in assuring that all requirements of renewal have been met.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

| Current section number | Current requirement | Proposed change and rationale |
|-------------------------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------|
| Chapter 20 Section 20 | Sets fees for renewal of licenses, permits and registrations | 1. Pharmacist active license – <u>due December 31</u> |
| | | 2. Pharmacist inactive license – <u>due December 31</u> |
| | | 3. Pharmacy technician registration – <u>due December 31</u> |
| | | 4. Pharmacy permit – <u>due April 30</u> |
| | | 5. Physician permit to practice pharmacy – <u>due February 28</u> |
| | | 6. Medical equipment supplier permit – <u>due February 28</u> |
| | | 7. Humane society permit – <u>due February 28</u> |
| | | 8. Nonresident pharmacy – <u>due April 30</u> |
| | | 9. Controlled substances registrations – <u>due February 28</u> |
| Chapter 50 Section 20 | Sets fees for renewal of manufacturers, wholesale distributors, and warehouse | Sets a renewal date of February 28 of each year |

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency

has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

The alternative would be to leave the current date in statute, but this will require either additional expenditures for temporary staff during this time period, or may result in licenses not being renewed before they expire. This also may result in staff turnover, because the Board has not, in the past several years, been in the position of allowing staff to use leave during this time period which coincides with the holiday season.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elizabeth Scott Russell, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or to scotti.russell@dhp.virginia.gov or to (804) 527-4472. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period on the Notice of Intended Regulatory Action.

After the publication of proposed regulations replacing emergency regulations, a public hearing will be held. Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family and family stability.